DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 12,2014

Distar, LLC
C/O Janeen Vilven-Doggett, PhD., J.D.
Peacock Myers, P.C.
201 Third Street NW, Suite 1340
Albuquerque, New Mexico 87102

Re: K140663
Trade/Device Name: Adjustable Therasnore
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: II
Product Code: LRK
Dated: September 12, 2014
Received: September 15, 2014

Dear Janeen Vilven- Doggett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140663

Device Name
Adjustable Therasnore

Indications for Use *(Describe)*
Adjustable TheraSnore appliance is indicated for the treatment of snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary 21 (CFR 807.92)
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510(K) Number: K140663

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Date Prepared: March 14, 2014

Device Classification

Device Name/
Trade Name: ADJUSTABLE THERASNORE

Common Name: Mandibular advancement device

Classification Name: Intra Oral Devices for Snoring and Intra Oral Devices for Snoring and Obstructive Sleep Apnea

CDRH Regulation: (21 CFR 872.5570)

CDRH Regulatory Class: II

CDRH Panel: Dental

Product Code: LRK
Subsequent Product Code: LQZ

Device Description: The Adjustable Therasnore appliance of this submission ("Subject Device") is an intraoral mandibular repositioning device used during sleep to reduce snoring and treat mild to moderate obstructive sleep apnea in adults (OSA). The Subject Device consists of an upper and a lower tray. The trays snap together and lock by means of a locking mechanism. The upper and lower trays snap together by means of four interlocking mechanisms, or railways which allow 1.5 mm incremental adjustments in a forward and backward fashion. The lower tray can be advanced up to

a maximum of 10 mm forward relative to the upper tray. The upper tray fits against the upper teeth and the lower tray fits against the lower teeth. The Subject Device when positioned on the teeth with the mandible in a forward position functions as a mandibular repositioner and acts to increase the patient's pharyngeal space which improves their ability to exchange air during sleep. The Subject Device is a boil and bite appliance consisting of an upper tray designed to fit over the teeth of the maxilla and a lower tray that fits to the lower incisors and prevents the tongue and mandible from falling back during sleep. The Subject Device is worn on the maxillary arch and covers the entire maxillary arch. Each tray is made from a hard acrylic material and a soft thermal plastic. The Subject Device is custom fitted for each patient by a doctor or dentist once the appliance is extracted from the heated water, cooled to the touch and the upper and lower trays are soft and pliable. This pliability allows the physician or dentist to fit the appliance to the upper and lower teeth of the patient when the patient pushes the mandible slightly forward into the appropriate position and the upper and lower tray are locked together. After this custom fitting, the Subject Device when in the patient's mouth, repositions the mandible in a slightly protruded forward position for as long as the Subject Device is worn. The appliance is provided to the patient on the same day of the fitting.

Intended Use: The Adjustable Therasnore appliance is indicated for the treatment of snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

Target Population: Patients 18 years of age or older who have a problem with snoring or obstructive sleep apnea (OSA).

Environment of Use: The device is intended for use by patients at home and in sleep laboratories.

Predicate Device:

Device Trade Name	Manufacturer	510(k) Reference Number	Product Code
PureSleep	Sleep Science Partners Inc.	K113022	LRK
Adjustable Therasnore	Distar, LLC	K973038	LRK

Technical Characteristics Compared to Predicate:

A comparison of the technological characteristics of the Subject Device and the predicate devices has been performed. The results of this comparison demonstrate the Subject Device is equivalent to the predicate devices.

Substantial Equivalence Discussion

The Subject Device is believed to be substantially equivalent to the predicate devices. The Subject Device and the predicate devices function as a mandibular repositioner which displace the patient's mandible during sleep. The mechanical components of the Subject Device and the predicate devices are similar, i.e. they include an upper and lower appliance component and a locking mechanism that is designed to advance the position of the lower component in relation to the upper component, thereby advancing the mandible. As with the (K973038) predicate device, the Subject Device is customized to fit each patient, and the mandibular advancement is adjusted by the dentist or physician at the time of fitting. The contact surfaces of the Subject Device and the predicate devices are made of hard resin with a softer plastic lining that is moldable when heated. The Subject Device is made from the same material and has the same mechanism of action as the Adjustable Therasnore predicate (K973038) which has received indication of use for snoring. The published literature and the cleared predicate devices justify the rationale for expanding the intended use from snoring to treat mild to moderate obstructive sleep apnea.

Summary of Non-Clinical Testing:

The submission includes data regarding the physical properties of the materials used in the Subject Device. The dental hard plastic, soft plastic lining material attached thereto and the locking mechanism used to manufacture the Subject Device have all been granted prior 510(k) approval for use in manufacture of dental appliances (K973038). The risks have been identified according to guidance document titled "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea: Guidance for Industry and FDA". The risks have been mitigated with appropriate labelling.

Summary of Clinical Testing

Clinical evaluation and observation in forty-three (43) patients with obstructive sleep apnea were treated with the Subject Device and showed, on average, in patients with mild to moderate obstructive sleep apnea a significantly improved respiratory disturbance index, improved oxygen saturation levels and decrease in the duration of apneic events.

CONCLUSION

The construction, intended use and mode of operation of the Subject Device is substantially similar and equivalent to the predicate devices.